QUORUM
REVIEW INC.
An Institutional Review Board

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May 26, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA's Draft Guidance for Industry on Using a Centralized IRB Review Process in Multicenter Clinical Trials [Docket No. 2005D-0103]

Dear Sir/Madam:

Quorum Review, Inc. ("Quorum") is pleased to provide comments on the issues raised in the Food and Drug Administration's ("FDA") Draft Guidance for Industry on Using a Centralized IRB Review Process in Multicenter Clinical Trials (the "Draft Guidance").[1] Quorum is an independent institutional review board ("IRB") located in Seattle, Washington and works with over 7,000 principal investigators nationwide. Quorum reviews clinical research that is governed by the FDA regulations and provides IRB oversight primarily for research sites that are not affiliated with an institution. Quorum also is a member of the Consortium of Independent Review Boards ("CIRB") and supports the comments submitted by CIRB on this same date.

This Draft Guidance is primarily directed at the "centralized" IRB review process, in which a central IRB either assumes jurisdiction from or shares jurisdiction with a local IRB.[2] We appreciate the fact that the Draft Guidance acknowledges the distinction between "centralized" review and the review of unaffiliated sites by a "central," unaffiliated IRB.[3] The centralized review process encompasses complex relationships among institutions and investigators who are frequently employed, supervised and/or credentialed by such institutions. The Draft Guidance appropriately acknowledges the need for careful documentation of such relationships. The Draft Guidance also acknowledges that central IRB review of unaffiliated sites share many, although not all, of the same issues. We encourage the FDA to continue to recognize and refine upon this distinction.

Second, Quorum agrees that membership diversity is a key mechanism by which a central IRB can appropriately address local aspects of IRB review.[4] Diversity of IRB membership along gender, cultural, ethnic, religious, socio-economic, professional and even geographic lines

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[1] *See* 70 Fed. Reg. 15635 (March 28, 2005).
[2] *See* Section II of the Draft Guidance ("A centralized IRB review process is an agreement in which multiple study sites in a multicenter trial rely, in whole or in part, on the review of an IRB other than the IRB that ordinarily would be responsible for review of research conducted at that location (i.e., the IRB for the institution with which the site is affiliated)").
[3] *See* Section VII of the Draft Guidance ("At clinical sites in a multicenter trial that are not already affiliated with an IRB, investigators and sponsors rely on the review and oversight of a central IRB").
[4] *See* Section IV of the Draft Guidance.

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allows a central IRB to comprehensively consider the local mores of a diverse participant population. Moreover, diversity of IRB membership allows a central IRB to take into account the "local" considerations of the wide-ranging and varied research sites and communities it serves.

The Draft Guidance devotes some discussion to the issue of "community attitudes."[5] Quorum encourages the FDA to expand upon the notion that a "community" can be defined as a community of *similarly situated individuals*, such as individuals who share a certain disease.[6] For central, unaffiliated IRBs who oversee large, multicenter clinical trials comprised of a participant population that spans state or even national borders, it is appropriate and essential to consider human commonalities that are not confined to geographic location alone.

In fact, Quorum questions the usefulness of the notion that an IRB must be aware of the "community attitudes" specific to a particular geographic locale. Attitudes toward research appear to vary more significantly among groups of individuals with different education levels, income levels, religious backgrounds and disease condition than they vary among geographic locations.

Instead, other local factors are critical in assessing human subject protection issues raised by proposed research. These factors include:

- The training and expertise of the principal investigator;
- The resources of the particular site; and
- The characteristics of the population from which the investigator will solicit participants.

For example, a multisite study could include two different principal investigators in one city. A consultant might report on a single set of community attitudes towards research in that city. However, if one investigator in that city intends to solicit participants from his or her own suburban clinical practice while another intends to solicit from a nearby homeless shelter, the IRB must consider significantly different local factors prior to approving the research.

In summary, Quorum concurs with the variety of mechanisms described in the Draft Guidance for a central IRB to become knowledgeable of the local factors affecting the research it oversees. The concept of a "community" that incorporates commonalities that transcend geographic bounds is helpful for central IRBs who are striving to appropriately address the concerns of the participant populations over which they have oversight. Finally, Quorum agrees with the FDA that a diversity of IRB membership is paramount in ensuring that a central IRB discharges its responsibilities with the respect of the communities it serves.

Quorum thanks the FDA for the opportunity to comment on this crucial matter. Please do not hesitate to contact me if you have any questions.

Sincerely,

Mark Mynhier
CEO, Quorum Review, Inc.

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[5] 21 C.F.R. 56.107(a).
[6] See Draft Guidance, n.10